Sheet

K

Substitute for form 1449A/PTO



PTO/SB/08A (08-00)
Approved for use through 10/31/2002, 0MB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Complete if Known Application Number 09/554,533 Filing Date November 13, First Named Inventor Beeley, Nigel Grow Art Unit To be assigned.

of

ANT	Application ( uniform	09/554,533		
AINI	Filing Date	November 13, 1998		
	First Named Inventor	Beeley, Nigel Robert Arnold		
	Group Art Unit	To be assigned		
	Examiner Name	To be assigned		
5	Attorney Docket Number	030639.0043.UTL2		

F	Cite	U.S. Patent Docume	ent	None of Bosons of Applicati	Date of Publication	Pages, Columns, Lines, Where Relevant
Examiner Initials *	No.	Number Kind (if kn	Code <sup>2</sup> own)	Name of Patentee or Applicant of Cited Document	of Cited Document MMDDYYYY	Passages or Relevant Figures Appear
SL	AA	5,118,666		Habener	06/02/1992	
Ī	AB	5,120,712		Habener	06/09/1992	
	AC	5,424,286		Eng	06/13/1995	
	AD	5,512,549		Chen	04/30/1996	
	AE	5,545,618		Buckley	08/13/1995	
	AF	5,574,008		Johnson	11/12/1996	<del></del>
	AG	5,686,511		Bobo	11/11/1997	
SL	AH	6,191,102	B1	DiMarchi et al.	02/20/2001	

Ei	Cita	Foreign	Patent Document		Name of December 4 - 15 - 1	Date of Publication	Pages, Columns, Lines,	
Examiner Initials *	Cite No.	Office <sup>3</sup> · Number <sup>4</sup> Kind Code <sup>3</sup> (if known)		Name of Patentee or Applicant of Cited Document	of Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	1¢	
SL	AI	wo	9011296		Habener	10/04/1990		Т
	AJ	wo	9111457		Buckley	08/08/1991		T
	AK	wo	9318786		Efendic	09/30/1993		Т
	AL	wo	9325579		Andrews	12/23/1993		Т
	AM	wo	9805351	A1	Amylin Pharmaceuticals, Inc.	02/12/1998		
	AN	wo	9819698	A1	Eli Lilly and Company	05/14/1998		1
	AO	wo	9830231	A1	Amylin Pharmaceuticals, Inc.	07/16/1998		
SL	AP	wo	9907404	Al	Amylin Pharmaceuticals, Inc.	02/18/1999		

Examiner Signature	/Samuel Liu/	Date Considered	07/05/2006

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>1</sup>See attached Kinds of U.S. Patent Documents. <sup>1</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid 0MB control number.

\$	substitute for form 1449A/PTO			I		
	NFORMATION	DIC	or Oction	Complete if Known		
i				Application Number	09/554,533	
	STATEMENT BY	AP	PLICANI	Filing Date	November 13, 1998	
	(use as many sheets a	nt n <i>oca</i> t	sani)	First Named Inventor	Beeley, Nigel Robert Arnold	
	(use us many sneeds t	is neves	sary)	Group Art Unit	To be assigned	
				Examiner Name	To be assigned	
Sheet	2	of	5	Attorney Docket Number	030639.0043.UTL2	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SL	AQ	ADELHORST, K., et al., "Structure-activity Studies of Glucagon-like Peptide-1 (GLP-1)," J. Biol. Chem., 269(9):6275-8 (1994)	) E
	AR	BARTLETT, et al., "Inhibition of Chymotrypsin by Phosphonate and Phosphonamidate Peptide Analogs," <u>Bioorg. Chem.</u> , 14:356-377 (1986)	H CE
	AS	BHAVSAR, "Inhibition of Gastric Emptying and of Food Intake Appear to Be Independently Controlled in Rodents," Soc. Neurosci. Abst., 21:460 (188.8)(1995)	LECH CENTER 1600/2900
	AT	COHEN, et al., The Pico Tag Method: A Manual of Advanced Techniques for Amino Acid Analysis, pp. 11-52, Millipore Corporation (1989)	00/2
	AU	D'ALESSIO, et al., "Elimination of the Action of Glucagon-like Peptide 1 Causes an Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons," J. Clin. Invest., 97:133-38 (1996)	8
	AV	EISSELE, et al., "Rat Gastric Somatostatin and Gastrin Release: Interactions of Exendin-4 and Truncated Glucagon-Like Peptide-1 (GLP-1) Amide," <u>Life Sci.</u> , 55:629-34 (1994)	
	AW	ENG, et al., "Isolation and Characterization of Exendin-4, an Exendin-3 Analogue, from <i>Heloderma suspectum</i> Venom," <u>J. Biol. Chem.</u> , 267:7402-05 (1992)	
	AX	ENG, et al., "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom," <u>J. Biol. Chem.</u> , 265:20259-62 (1990)	
	AY	FEHMANN, et al., "Stable Expression of the Rat GLP-I Receptor in CHO Cells: Activation and Binding Characteristics Utilizing GLP-I(7-36)-Amide, Oxyntomodulin, Exendin-4, and Exendin(9-39)," Peptides, 15(3):453-6 (1994)	
SL	AZ	FERGUSON, et al., "Cell-Surface Anchoring of Proteins Via Glycosylphosphatidylinositol Structures," <u>Annu. Rev. Biochem.</u> , 57:285-320 (1988)	

Examiner Signature	/Samuel Liu/	Date Considered	07/05/2006	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. 0MB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE Application Number 09/554,533 STATEMENT BY APPLICANT Filing Date November 13, 1998 First Named Inventor Beeley, Nigel Robert Arnold (use as many sheets as necessary) Group Art Unit To be assigned Examiner Name To be assigned Attorney Docket Number of 030639.0043.UTL2 Sheet 5

S	L BA	GOKE, et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of	
Н	BB	Insulin-secreting β-Cells," J. Biol. Chem., 268:19650-55 (1993)	
	ВВ	GOLDSTONE, et al., "Leptin Interacts with Glucagon-like Peptide-1 Neurons to	4
	}	Reduce Food Intake and Body Weight in Rodents," <u>FEBS Letters</u> , 415:134-138	## 12 12 13 13 14 14 15 15 16 16 16 16 16 16 16 16 16 16 16 16 16
		(1997)	
	BC	HALAAS, J.L., et al., "Weight-Reducing Effects of the Plasma Protein Encoded	CENITER 1600/2900
		by the Obese Gene," <u>Science</u> , 269:543-546 (1995)	₹
	BD	KODAMA, J., et al., "Effect of Captopril on Glucose Concentration Possible	中
		Role of Augmented Postprandial Forearm Blood Flow," <u>Diabetes Care</u> ,	<b>I</b>
		13(11):1109-1111 (1990)	
	BE	KOLLIGS, et al., "Reduction of the Incretin Effect in Rats by the Glucagon-like	#
		Peptide-1 Receptor Antagonist Exendin (9-39) Amide," <u>Diabetes</u> , 44:16-19	\$
		(1995)	
	BF	LEIBEL, R.L., et al., "Changes in Energy Expenditure Resulting from Altered	
		Body Weight," New England Journal of Medicine, 332(10):621-628 (1995)	
	BG	LITHELL, et al., "Insulin Sensitivity in Newly Detected Hypertensive Patients:	
		Influence of Captopril and Other Antihypertensive Agents on Insulin Sensitivity	
		and Related Biological Parameters," J. Cardiovasc. Pharmacol., 15 (Supp 5):S46-	
		S52 (1990)	
	BH	MALHOTRA, et al., "Exendin-4, a New Peptide from Heloderma suspectum	
		Venom, Potentiates Cholecystokinin-induced Amylase Release from Rat	Ì
		Pancreatic Acini," Regulatory Peptides, 41:149-56 (1992)	1
	BI	MONTROSE-RAFIZADEH, et al., "Structure-function Analysis of Exendin-4/	
		GLP-1 Analogs," <u>Diabetes</u> , 45 (Suppl. 2):152A (1996)	
	BJ	NAVARRO, M. et al., "Colocalization of Glucagon-Like Peptide-1 (GLP-1)	
ŀ		Receptors, Glucose Transporter GLUT-2, and Glucokinase mRNAs in Rat	i
SL	.	Hypothalamic Cells: Evidence for a Role of GLP-1 Receptor Agonists as an	
		Inhibitory Signal for Food and Water Intake," <u>Journal of Neurochemistry</u> ,	
ı		67:1982-1991 (1996)	
	ВК	O'HALLORAN, et al., "Glucagon-like Peptide-1 (7-36)-NH <sub>2</sub> : a Physiological	
4		1	

Examiner Signature	/Samuel Liu/	Date Considered	07/05/2006
			1

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. 0MB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

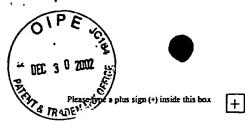
	Substitute for form 1449A/PTO				
	INFORMATION	INIC	CI OSIME		Complete if Known
				Application Number	09/554,533
	STATEMENT B	YAP	PLICANI	Filing Date	November 13, 1998
	(use as many sheet		econul .	First Named Inventor	Beeley, Nigel Robert Arnold
	(use as many sneed	a us nece	ssury)	Group Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	4	of	5	Attorney Docket Number	030639.0043.UTL2

		Inhibitor of Gastric Acid Secretion in Man," J. Endocrinol., 126(1):169-73 (1990)	
SL	BL	ØRSKOV, et al., "Biological Effects and Metabolic Rates of Glucagonlike	
ЭH		Peptide-1 7-36 Amide and Glucagonlike Peptide-1 7-37 in Healthy Subjects Are	
		Indistinguishable," <u>Diabetes</u> , 42:658-61 (1993)	
	BM	PELLEYMOUNTER, et al., "Effects of the Obese Gene Product on Body Weight	)H
		Regulation in ob/ob Mice," Science, 269:540-543 (1995)	ECHICENTEM 1600/290
	BN	RAUFMAN, et al., "Truncated Glucagon-like Peptide-1 Interacts with Exendin	70
		Receptors in Dispersed Acini from Guinea Pig Pancreas," J. Biol. Chem.,	Ë
		267:21432-37 (1992)	<u> </u>
	BO	RAUFMAN, et al., "Exendin-3, a Novel Peptide from Heloderma horridum	1
		Venom, Interacts with Vasoactive Intestinal Peptide Receptors and a Newly	2
		Described Receptor on Dispersed Acini from Guinea Pig Pancreas," J. Biol.	2
		<u>Chem.</u> , 266:2897-902 (1991)	٣
	BP	SCHEPP, et al., "Exendin-4 and exendin-(9-39)NH <sub>2</sub> : Agonist and Antagonist,	J
		Respectively, at the Rat Parietal Cell Receptor for Glucagon-like Peptide-1-(7-	
		36)NH <sub>2</sub> ," <u>Eur. J. Pharm.</u> , 269:183-91 (1994)	
	BQ	SCHJOLDAGER, et al., "GLP-1 (Glucagon-like Peptide 1) and Truncated GLP-	
		1, Fragments of Human Proglucagon, Inhibit Gastric Acid Secretion in Humans,"	
		<u>Dig. Dis. Sci.,</u> 34 (5):703-8 (1989)	
	BR	SINGH, et al., "Use of <sup>125</sup> I-[Y <sup>39</sup> ]Exendin-4 to Characterize Exendin Receptors on	
		Dispersed Pancreatic Acini and Gastric Chief Cells from Guinea Pig," Regul.	
		<u>Pept.</u> , 53:47-59 (1994)	
	BS	THORENS, "Expression Cloning of the Pancreatic B Cell Receptor for the	
		Gluco-Incretin Hormone Glucagon-like Peptide 1," Proc. Natl. Acad. Sci. USA,	
		89:8641-45 (1992)	
	BT	THORENS, et al., "Cloning and Functional Expression of the Human Islet GLP-1	
		Receptor," <u>Diabetes</u> , 42 (11):1678-82 (1993)	
	BU	TURTON, et al., "A Role for Glucagon-Like Peptide-1 in the Central Regulation	
		of Feeding," Nature, 379:69-72 (1996)	
SL	BV	VEALE, P.R., et al., "The Presence of Islet Amyloid Polypeptide/Calcitonin Gen-	
		Related Peptide/Salmon Calcitonin Binding Sites in the Rat Nucleus	

Examiner Signature	/Samuel Liu/	Date Considered	07/05/2006
			\

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (08-00) Approved for use through 10/31/2002. 0MB 0651-0031

U.S. Patrut and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute for form 1449A/PTO					
	INFORMATION :	DIC	CLOCIDE	Complete if Known		
				Application Number	09/554,533	
	STATEMENT BY	AP	PLICANI	Filing Date	November 13, 1998	
	(use as many sheets a	11 110000	sanı)	First Named Inventor	Beeley, Nigel Robert Arnold	
	(and an many sheets to	J neces	34,77	Group Art Unit	To be assigned	
				Examiner Name	To be assigned	
Sheet	5	of	5	Attorney Docket Number	030639.0043.UTL2	

		Accumbens," European Journal of Pharmacology, 262:133-141 (1994)					
SL	BW	WANG, et al., "Glucagon-like Peptide-1 Is a Physiological Incretin in Rat," <u>J.</u>					
		Clin. Invest., 95:417-21 (1995)					
	BX	WATSON, N., et al., "Effects of Captopril on Glucose Tolerance in Elderly					
	Patients with Congestive Cardiac Failure," Current Medical Research and						
		Opinion, 12(6):374-378 (1991)					
	BW	WETTERGREN, et al., "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits					
	<u> </u>	Gastric and Pancreatic Functions in Man," Dig. Dis. Sci., 38(4):665-73 (1993)					
	BZ	WILLMS, et al., "Gastric Emptying, Glucose Responses, and Insulin Secretion					
<b>!</b>		after a Liquid Test Mel: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-					
	l	(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," J. Clin.					
	<u></u>	Endocrinol. Metab., 81(1):327-32 (1996)					
SL	CAZ	YOUNG, et al., Program and Abstracts, 10th International Congress of					
		Endocrinology June 12-15, 1996, San Francisco, p. 419 (P2-58)					

## **RECEIVED**

JAN 0 2 2003

**TECH CENTER 1600/2900** 

Examiner I	/Common 1 T dos /	Date	
2.00	/Samuel Liu/	Date	07/05/200 <i>6</i> I
Signature	,	Compident	07/05/2006
Digitature		Considered	• •• - • - • •

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.